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March 15, 2019

The Honorable Colm F. Connolly
J. Caleb Boggs Federal Building
Wilmington, DE 19801-3555

Re: **Genentech, Inc. v. Amgen Inc., C.A. No. 17-1407-CFC (D. Del.)**
(consolidated)

Dear Judge Connolly:

This letter responds to the Court's Order of March 13 (D.I. 300).

Amgen's [REDACTED] accused of infringement in the new complaint concerns the manufacture of Mvasi [REDACTED]

[REDACTED]¹ Plaintiffs believe the [REDACTED] under 42 U.S.C. § 262(l); that it infringes pursuant to 35 U.S.C. § 271(e); and that the BPCIA for multiple reasons requires that claim to be brought in a new complaint.

Because the Protective Order permits a party's "confidential" information to be used only for new lawsuits that "aris[e] from Defendants' filing of Biologics License Application No. 761028," *i.e.*, the aBLA Amgen filed for approval of Mvasi manufactured in Thousand Oaks, Paragraph 28 should be amended as Plaintiffs have proposed.

Amgen seems to dispute that its [REDACTED] for purposes of 42 U.S.C. § 262(l). At the same time, however, Amgen contends that filing the new complaint based on it would be a misuse of information Amgen produced in discovery it designated "confidential."

Amgen's position is puzzling. If the [REDACTED] for purposes of the BPCIA, there is no reasonable objection under the Protective Order to filing suit over it. Regardless, Genentech in January provided Amgen a draft of the new complaint and sought Amgen's consent to amend Paragraph 28 to allow its filing. The new complaint asserts claims under § 271(a), (e), and (g) over [REDACTED]

¹ [REDACTED]

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[REDACTED]
[REDACTED]. Amgen declined.

The complaint also includes claims under § 271(a) and (g) arising from the infringing manufacture [REDACTED] of a different product. Discovery strongly suggests Amgen uses [REDACTED]

[REDACTED] As explained in Plaintiffs' letter brief, courts routinely amend protective orders to allow plaintiffs to pursue claims revealed in discovery. D.I. 291 at 2; *see also* 8A Fed. Prac. & Proc. Civ. § 2044.1 (3d ed.) (discussing "long line of cases recognizing the propriety of access to the fruits of one litigation to facilitate the preparation of other cases").

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: All counsel of record (via CM/ECF)

WORD COUNT CERTIFICATION

I hereby certify that the substantive text of the foregoing letter contains 387 words, as counted by the Word Count feature of Microsoft Word.

/s/ Daniel M. Silver

Daniel M. Silver (# 4758)